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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|-------------|--|---------------------|---------------------|--|
| 10/621,543 | 07/18/2003 | Minoru Suzuki | 027550-119 | 2474 | |
| 7590 | 07/02/2008 | BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404 | | | |
| | | | | EXAMINER | |
| | | | | VU, QUYNH-NHU HOANG | |
| ART UNIT | | PAPER NUMBER | | | |
| | | 3763 | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/621,543 | Applicant(s) SUZUKI ET AL. |
| | Examiner QUYNH-NHU H. VU | Art Unit 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 January 2007.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3-7,16,17 and 20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 3-7,16,17 and 20 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/1449)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendment

Amendment filed on 01/25/07 has been entered.

Claims 3-7, 16-17, 20 are present for examination.

Claims 1-2, 8-15, 18-19 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Suzuki et al. (US 6,595,948). It is noted that Examiner made typo error 102 (b) last Previous Action mailed on 8/25/06.

Suzuki et al discloses a peritoneal dialysis apparatus (2) including at least one dialysis fluid container filled (4) with a dialysis fluid, a dialysis fluid circuit containing at least one drained fluid container (6) for recovering the dialysis fluid, fluid delivery means (7) for delivering the dialysis fluid with the dialysis fluid container as a start point or the drained fluid container as an end point, input means (see fig. 26) for inputting dialysis conditions including an amount of infusion fluid, a staying time, the number of cycles, a total dialysis time, and a total amount of infusion fluid, and display means for displaying the inputted dialysis conditions, wherein dialysis is performed by delivering the dialysis fluid to a patient by the delivery means and recovering the drained fluid and; the apparatus includes means for calculating a dialysis end time (dialysis time and planned dialysis end time, col. 18, line33) from a desired dialysis time while the inputted set-up therapy start time is taken as a preferential value.

Regarding claims 4-5, Examiner interprets the limitation: "means for deciding whether or not fluid infusion is performed for a fluid infusion time exceeding the calculated fluid infusion time by more than a

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predetermined time" as abnormal/error stage whenever the fluid infusion times is more than the calculated fluid infusion time. Similarly, Suzuki discloses that the abnormal states such as closure of fluid infusing time (in other words, fluid infusion is still continuing or exceeding the expected/calculated fluid infusion time), defective fluid infusing, closure of additional fluid infusing time (col. 19, line 33-col. 20, line 52.); a various types of sensors 16 detect an abnormality, the screen automatically shifts to screen displaying an abnormal state, and what kind of abnormality has occurred is sequentially displayed (also see col. 18, line 17-col. 20, line 52 for supporting these limitation above).

Regarding claims 6-7, Examiner interprets the limitation: "means for deciding whether or not fluid drainage is performed for a fluid drainage time exceeding the calculated fluid drainage time by more than a predetermined time" as abnormal/error state whenever the fluid drainage times is more than the calculated fluid drainage time. Similarly, Suzuki discloses the closure of fluid draining line (in other words, fluid drainage is still continuing or exceeding the expected/calculated fluid drainage time), defective fluid draining

In order to inform the abnormal state, Figs. 27 shows that on screens 550 to 554, message are displayed as a still image or motion image including characters while producing a voice guide or background color to indicated by hatched portions, so as inform the user of the abnormal state; a means for generating an alarm (Fig. 27) and wherein the display device is a portable terminal (also see col. 18, line 17-col. 20, line 52 for supporting these limitation above).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 6,595,948) or Suzuki et al. (US 2002/0045851) in view of Bimbaum (US 2003/0028116).

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Suzuki discloses a peritoneal dialysis apparatus (2) including at least one dialysis fluid container filled (4) with a dialysis fluid, a dialysis fluid circuit containing at least one drained fluid container (6) for recovering the dialysis fluid, fluid delivery means (7) for delivering the dialysis fluid with the dialysis fluid container as a start point or the drained fluid container as an end point, input means and display means (see fig. 26) for inputting dialysis conditions; wherein dialysis is performed by delivering the dialysis fluid to a patient by the delivery means 7 and recovering the drained fluid (6); the apparatus further comprising: means for selecting a temporary separation mode during therapy to temporarily stop the therapy (Step 550 to 554 of Fig. 27).

Suzuki does not disclose a means for displaying a residual staying time after the temporary separation mode is selected.

Bimbaum teaches or suggests that a caloric exercise monitor comprising the monitor can display the remaining exercise times/residual times (15 mins) require to reach the exercise goal (para [0041]).

Since the device of Suzuki discloses the displaying such as stay time, dialysis time, planned end time.

Thus, it would have been obvious to a person of ordinary skill in the art to update older dialysis devices such as shown in Suzuki with another feature that are commonly available and understood in the art as shown in Bimbaum, in order to gain the commonly understood benefits of such adaptation and simplified operation and the user can view the time remaining to reach the dialysis process.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 2002/0045851) in view of Bimbaum (US 2003/0028116) and further in view of Flinchbaugh (US 2002/0139419).

Suzuki in view of Bimbaum discloses the invention substantially as claimed. Suzuki in view of Bimbaum does not disclose that the means for displaying the residual time is comprises a portable terminal.

Flinchbaugh discloses a programmable apparatus can be used in kidney dialysis (see abstract) comprising: a display can include a transceiver for allowing for remote actuation of the device and/or for

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sending device date to remote locales, such as but not limited to a nurse station, and the like. The transceiver can be either or both wireless... (para [0051]).

Thus, it would have been obvious to a person of ordinary skill in the art to update older dialysis devices such as shown in Suzuki in view of Bimbaum with another feature that are commonly available and understood in the art as shown in Flinchbaugh, in order to gain the commonly understood benefits of such adaptation and simplified and enhanced operation, and the nurse/doctor does not to be attending next to the patient all the times but they are able to know the condition of the patients.

Response to Arguments

Applicant's arguments filed 01/25/07 have been fully considered but they are not persuasive.

Applicant argues that Suzuki et al. is devoid of any disclosure that the apparatus permits selection of a therapy mode in which at least the staying time per cycle is calculated based on the total dialysis time, the amount of infusion fluid per cycle and the number of cycles which are inputted in the input means.

In response, Applicant claims that an inputting dialysis conditions including a staying time,...the total dialysis time. In other words, it can be read as the total dialysis times in 1, 2 or many cycles. But Applicant does not disclose that "the total dialysis time per cycle".

Furthermore, Suzuki clearly discloses in Fig. 16 or in col. 18, lines 28-37 that:

400a. Successively, the screen automatically shifts to a screen 503. On this screen, parameters necessary for peritoneal dialysis, e.g., treatment pattern, initial amount of drained fluid, amount of infused fluid, stay time in the peritoneal cavity, number of cycles, final shot amount of infused fluid, whether the final concentration is altered, dialysis time, planned dialysis end time, and total amount of dialysis fluid, are displayed as the previous dialysis data. If 10 the current treatment is to be performed with the previous 15 conditions, the user touches a touch key 506 "NEXT" to advance to the screen of FIG. 23.

The paragraph above is clearly support for Suzuki fully covered the claimed limitations above.

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Applicant's arguments with respect to claims 4-7, 16-17 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763